Procedures Manual Bovine Spongiform Encephalopathy (BSE) Ongoing Surveillance Plan

Ongoing Surveillance Plan Implementation

July 20, 2006

U.S. Department of Agriculture Animal and Plant Health Inspection Service Veterinary Services

Veterinary Services

APHIS • USDA

Introduction

Purpose

This document provides guidance and describes the procedure to be used for the National Bovine Spongiform Encephalopathy (BSE) Ongoing Surveillance Program. The principal purposes of ongoing BSE surveillance are to continue to assess and monitor change in the BSE status of U.S. cattle and to provide a mechanism for early detection of BSE. This program is designed to exceed the requirements for sample points and numbers necessary meet the OIE Surveillance Standards. The goal of this program is to assure the detection of BSE and use a design prevalence estimate of one detectable case per one million adult cattle. An appropriate number of cattle from the subpopulation defined in the OIE surveillance streams and targeted sample criteria established in the ongoing surveillance plan will be tested to allow the highest probability of disease detection in order to continually assess the BSE status of U.S. cattle. In this respect, this document is meant to be dynamic and will be updated regularly as necessary.

The purpose of this document is to clarify:

- The objectives of the overall program and the objective for each of the categories of animals to be sampled,
- Standard operating procedures for referring any case highly suspicious for BSE animal to the Area Veterinarian-in-Charge (AVIC) for investigation,
- Personal safety guidelines,
- Sampling methods that target high risk cattle,
- Information requirements with respect to sample collection,
- Shipping samples to a laboratory,
- Communication protocols, and
- Disposal of the carcass and offal.

Surveillance Plan Overview

The Animal and Plant Health Inspection Service (APHIS), in cooperation with the Food Safety and Inspection Service (FSIS), and the Food and Drug Administration (FDA), implemented an Enhanced BSE Surveillance Program that tested over 600,000 samples (June 2004 through March 2006) and found only two positive domestic cows, one each in Texas and Alabama. The results of enhanced surveillance indicate that while BSE is present, it is at an extremely low level in U.S. cattle. This warrants movement to a BSE Ongoing Surveillance Plan designed to detect disease should the prevalence rise above 1 case per 1,000,000 adult cattle. The BSE Ongoing Surveillance Plan is designed to exceed the accepted surveillance practices established by the World Organization for Animal Health (OIE) and reassure consumers and international trading partners of the BSE status of U.S. cattle. The surveillance plan will be continuously analyzed and periodically adjusted as needed to assure market confidence in U.S. cattle.

Targeted animals

Under the BSE Ongoing Plan state and federal field personnel will primarily be focused on collection of samples from cattle of any age or breed that exhibit CNS signs.

1. Cattle of Any Age with CNS Signs

This category includes:

- Cattle affected by illnesses that are refractory to treatment (including anorexia, loss
 of condition in spite of good appetite, pneumonia, decreased milk yield) and are
 displaying CNS or behavioral changes that are not of an acute nature (including
 apprehension, nervousness, excitability, aggression, head shyness, hypermetria,
 kicking when milked, difficulty in rising, excessive nose scratching, hesitation at
 gates/barriers);
- Cattle designated as "rabies suspects" (including rabies-negative cases from public health laboratories, and FSIS condemns for "CNS signs" or "rabies"; It also includes cattle highly suspicious for BSE as indicated by VS Memo 580.16 (Appendix A):
- Cattle displaying progressive neurological signs that cannot be attributed to infectious illness and are not responsive to treatment.

2. Cattle \geq 30 months of age that are condemned during antemortem inspection, or excluded from slaughter due to poor health status (unhealthy or dead due to illness or injury).

This category includes:

- Samples shall be collected from cattle 30 months of age or older, condemned on antemortem inspection at both State- and FSIS-inspected plants determined through use of an allocator tool. Sampling numbers will be determined prior to the commencement of the BSE Ongoing Surveillance Plan, and may be periodically adjusted during the sampling year. All cattle, regardless of age, condemned by FSIS upon antemortem inspection for CNS impairment will be sampled.
- Cattle for which sample collection occurs on-farm, at veterinary clinics, or at livestock sale or auction barns and that are dead, nonambulatory, or have clinical signs that may be associated with BSE. For those cattle that are dead prior to arrival of sampling personnel on-farm, additional clinical history must be collected.
- Cattle presented to veterinary diagnostic laboratories for necropsy or for ancillary diagnostics without a history of CNS signs but which had clinical signs that may be associated with BSE.

•	Samples will be collected specifically at renderers or 3D/4D facilities from cattle that
	are dead, nonambulatory, or sick. Collection of clinical history is preferable for these
	samples but is not required.

Targeted High-Risk Cattle for BSE According to Surveillance Stream

Surveillance Streams

Cattle targeted for ongoing surveillance can be divided into the following surveillance streams based on the sample source, the clinical information about the animal, and the condemnation code. These streams are consistent with the OIE surveillance stream categories as follows:

1. Clinical suspects – cattle of any age displaying behavioral or clinical signs consistent with BSE

Samples will be assigned to this surveillance stream if they are from cattle in a foreign animal disease investigation for CNS signs, were tested negative for rabies at a public health or veterinary diagnostic laboratory, had CNS signs or were condemned by FSIS for CNS signs or rabies, or if the likelihood ratio for clinical signs associated with BSE is above an appropriate cutoff value.

Animals considered to have clinical signs associated with BSE include those with illnesses that are refractory to treatment, and displaying progressive behavioral changes or neurological signs without other signs of infectious illness. Progressive behavioral changes may be demonstrated by excitability, persistent kicking when milked, changes in herd hierarchical status, and hesitation at doors, gates and barriers. Animals presenting these clinical signs are candidates for examination.

Most of these samples are anticipated to be collected from on-farm cattle. A substantial number will also be contributed by FSIS, veterinary diagnostic laboratories, and public health laboratories.

2. Casualty slaughter – since FSIS has no provisions for emergency slaughter, cattle > 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance, and are sent to slaughter will be condemned at antemortem inspection and sampled for BSE.

Samples will be assigned to this surveillance stream if the likelihood ratio for clinical signs being associated with BSE is below an appropriate cutoff value, and if the sample meets the OIE criteria for this stream.

Most of these samples are anticipated to be collected at FSIS slaughter plants or approved contracted off-site collection facilities. However, a considerable number will be contributed by other data sources such as on-farm and veterinary diagnostic laboratories.

3. Fallen stock - cattle \geq 30 months of age that are found dead on farm, or during transport to or at an abattoir.

Samples will be assigned to this surveillance stream if the likelihood ratio for clinical signs being associated with BSE is below an appropriate cutoff value, and if the sample meets the OIE criteria for this stream. These samples will only be accepted from FSIS inspected plants and rendering or 3D/4D facilities, and are anticipated to comprise a relatively small portion of the sample population.

Collection Sites

The BSE ongoing program has outlined six primary sites which will provide an adequate sampling of the major BSE surveillance streams.

- 1. On-Farm These samples may be collected by specially trained accredited veterinarians, federal or state employees (including animal health technicians), or VS-approved dead stock haulers. Under VS Area Office oversight, sample collectors with other qualifications may be enlisted when resources preclude the participation of aforementioned sample collectors in a given area. Although these samples may have a higher cost relative to other data sources, they are anticipated to have higher value to surveillance since the accuracy, quantity, and perceived validity of historical clinical signs data is superior relative to other data sources. Additionally, this source is important for capturing clinical suspects that would have not been presented to other data sources.
- **2. Veterinary Diagnostic Laboratories -** Cattle submitted for necropsy, or fresh whole brainstem submitted for ancillary diagnostics to veterinary diagnostic laboratories, including those not involved in BSE testing, will be sampled by specially trained laboratory personnel. Such samples are usually accompanied by significant historical information pertaining to clinical signs, and thus are of high value to surveillance.
- **3.** Public Health Laboratories All samples from cattle that are rabies suspects and test negative for rabies will be submitted for surveillance by laboratory personnel. All samples derived from this data source can be characterized as clinically suspicious for BSE, and thus are of high value to surveillance.
- **4. Miscellaneous** Miscellaneous sample sources will include veterinary clinics, livestock markets, and other sites where samples and corresponding clinical history information will be collected by veterinary professionals or government employees. These data sources are important for capturing clinical suspects that do not present to other collection sites.
- 5. Slaughter (FSIS) Samples shall be collected from cattle 30 months of age or older, condemned on antemortem inspection at both State and federally inspected slaughter plants. Sampling numbers will be determined prior to the commencement of the BSE Ongoing Surveillance Plan, and may be periodically adjusted during the sampling year. All cattle, regardless of age, condemned by FSIS upon antemortem inspection for CNS impairment will be sampled. Samples will be collected by FSIS employees

or designated off-site sample collection facilities. Most of these samples are anticipated to represent cattle belonging to the second most valuable surveillance stream ("casualty slaughter").

- 6. Facilities contracted to collect samples from cattle condemned at antemortem inspection by FSIS Samples derived from animals condemned at antemortem inspection may be collected by personnel of a contracted off-site collection facility. Under these circumstances, communication of clinical history and condemnation codes to the contracted facility is imperative.
- 7. Rendering or 3D/4D facilities In order to represent the "fallen stock" surveillance stream and a wide variety of data sources, 5,000 samples will be collected from targeted cattle presenting to rendering or 3D/4D facilities contracted for sample collection. A quota is selectively applied to this collection site type since the average point value per sample derived from this source is much lower than other enlisted collection site types.

Collection Site Type	Estimated percentage of samples to be collected for ongoing sampling	Personnel Submitting Samples
On-Farm	> 45%	State/Federal VMOs or AHTs
Veterinary Diagnostic Laboratories	< 5%	Private Veterinarians
Public Health Laboratories	< 0.1%	Private Veterinarians
Slaughter (FSIS)	< 15%	FSIS
Facilities contracted to collect samples from antimortem condemned animals sent to rendering.	> 33%	Contract Personnel or State/Federal Employees
Rendering or 3D/4D Facilities contracted to sample cattle that are dead, nonambulatory or sick.	< 9%	Contract Personnel or State/Federal Employees

Note: These percentages may fluctuate greatly on an area basis, but are included to show the overall expectation of the program and could serve to help target collection in certain areas.

Personal Safety

If BSE is transmissible to humans in the occupational setting, the most likely routes would be through contact with infective tissues through wounds or open lesions on the skin, contact with mucous membranes (eyes and mouth), or exceptionally, by swallowing. Transmission by the airborne route (i.e., by the inhalation of infectious airborne particles) is considered to be the least likely route of exposure. In naturally BSE affected cattle, the only tissues that have shown infectivity are the brain, retina, and spinal cord. In experimentally (orally) affected cattle, the distal ileum has also shown infectivity.

Because rabies, listeriosis, and other possible zoonotic diseases must be included in the differential diagnosis, brain and spinal cord collection from cattle with CNS clinical signs should be done carefully. The following precautions are generally applicable:

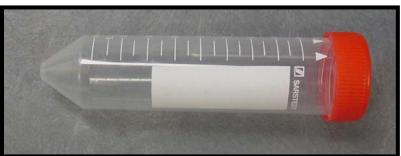
- Adhere to safe working practices and take extra precautions to avoid or minimize the use of tools and equipment likely to cause cuts, abrasions, or puncture wounds.
- Where use of such equipment is unavoidable, wear suitable protective clothing which includes disposable coveralls, aprons, heavy gloves and boots.
- Cover existing cuts, abrasions, and skin lesions on exposed skin with waterproof dressings.
- Use face protection such as a facemask and face shield or goggles to protect the mucous membranes of the eye, nose, and mouth from exposure to infective droplets or tissue fragments.
- Take steps to avoid the creation of aerosols and dusts when engaged in activities such as sawing through the skull bones.
- Wash hands and exposed skin before eating, drinking, smoking, taking medication, using the telephone, or going to the toilet.
- Wash and disinfect protective clothing and instruments thoroughly after use.

Detailed Sampling Procedures

Tools needed

- Knife and scissors
- Spoon (or other suitable device)
- Forceps
- Screw top plastic tubes (50ml)
- Fine point permanent marker
- Ball-point pen
- Pan or bucket for disinfecting instruments and rinsing gloved hands
- Bleach (disinfectant)
- Paper towels
- Trash bags
- Supply of BSE mailers (including frozen cold packs)
- May need scabbard, a steel and personal protective equipment





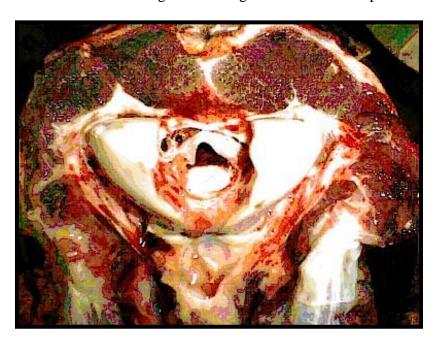
Getting a Sample of Sufficient Quality

Unless the sample is of sufficient quality, it will be unusable and not count towards the survey. An appropriate brainstem sample includes obex, and is affected with little contamination or postmortem decomposition. Sample collectors should submit samples that have questionable testability and allow laboratory technicians to decide if tissue integrity precludes testing. Samples that are affected with postmortem or post-collection decomposition such that they cannot be recognized as brainstem will not be tested by the diagnostic laboratory. If the sample is <u>obviously</u> not of sufficient quality (i.e., liquefied), STOP: DO NOT TAKE THE SAMPLE. This does NOT apply to samples taken from:

• animals that are highly suspicious for BSE or that involve an FAD investigation or are condemned for CNS reasons

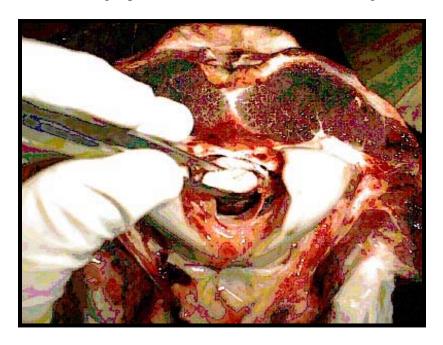
BSE Sampling Using A Spoon

- Place head upright
 - On head rack or barrel
 - On table edge
 - On the ground facing down if no other option

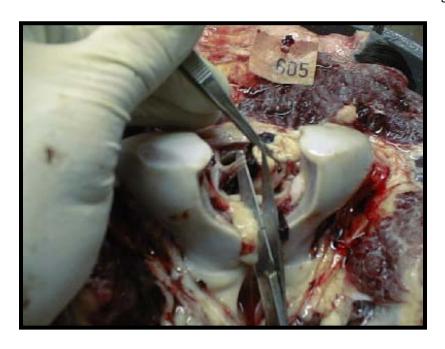


Step 2

- Grasp the spinal cord with forceps
- Use light pressure so that the tissue is not damaged

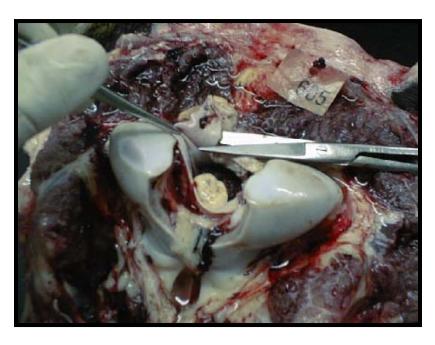


- Cut the dura mater & cranial nerves
- Cut down each side of the spinal cord about ½" or more
- Cut on the sides do not cut into the spinal cord
- Failure to sever cranial nerves is a common cause of damaged samples



Step 4

- With forceps and scissors remove as much dura mater as possible
- Dura mater removal allows better visualization and is needed for proper sample removal



- With light pressure use forceps to hold the spinal cord to the ventral part of the foramen
- Insert the spoon (inverted) on the dorsal part of the spinal cord to sever the cerebellum
- Remove the spoon



Step 6

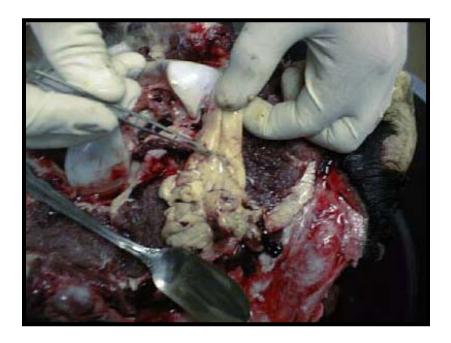
- With forceps lift the spinal cord dorsally and re-insert along the ventral surface of the spinal cord
- Lower the handle of the spoon to sever the cord/brain stem

• With constant upward pressure/dorsal movement of the front edge of the spoon, gently work the severed sample from the foramen



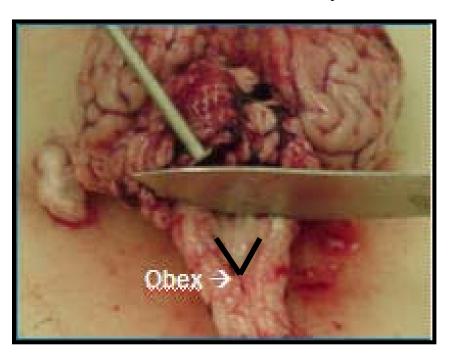
<u>Step 7</u>

- Complete removal of the sample from the foramen
- Clean off excess blood



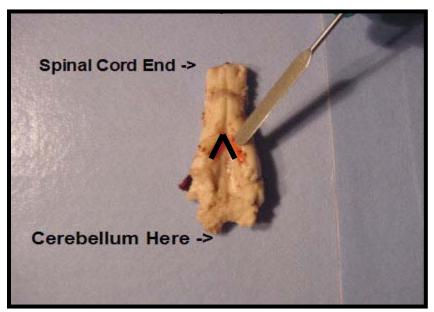
<u>Step 8</u>

- You should be able to identify the Obex area of the brain
- Make sure your samples contain the Obex
- The Obex MUST be collected for the sample to be used in BSE the surveillance data

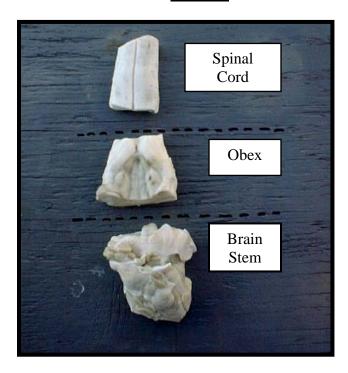


Note:

- The area marked in **black** is the location of the Motor Nucleus of the Vagus nerve
- The nucleus appears as "pink fleshy" areas
- This nucleus is the area we examine in the lab
- The pointer at the "V" is the Obex

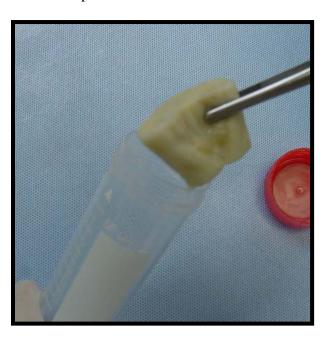


- Cut the samples as pictured
- The middle piece of tissue contains the Obex and the Motor Nucleus of the Vagus
- The Obex is the **key area**



Step 10

- Remember the sample will be *FRESH* tissue
- NO formalin
- Place the Obex in the supplied screw top tube
- Label the sample tube with:
 - Sample number (ex: 1,2,3,4)
 - Barcode ID label
- Dispose of non-submitted tissue with carcass



Identification and Recording of Samples

- Sample submitters must accurately record all relevant information on the USDA BSE Surveillance Submission Form, USDA BSE Surveillance Submission Continuation Form if used, and on each of the USDA BSE Surveillance Data Collection Forms.
- Animal Identification Recording
- All alpha characters (letters) of an Animal ID should be recorded in upper case (capitalized).
- When entering Animal ID for other than "Official" Tags, be sure to indicate the color on the Animal ID tag if applicable.
- When indicating the color of a particular type of ID, begin the Tag ID with the single capitalized letter indicating the color per table below, then include an underscore (_) followed immediately be the alphanumeric sequence of the ID
- Also substitute an underscore (_) without additional spaces, for each unreadable number/character in an ID.

- All types of ID on the animal, including those forms of identifications that are used in unique geographical areas or farming operations, should be recorded, collected, and maintained until the sample results are received for the animal.
- Note: Each ID field referenced on the electronic forms is limited to 15 alpha/numeric characters.

Official ID Documentation

- USDA metal eartag, Brucellosis vaccination eartag, Animal Identification Number (AIN) button eartag, and bangle eartag:
 - Enter the ID information in the appropriate box on the USDA BSE Surveillance Data Collection Form.
 - o No color indication is required.
 - o Enter up to two ID's in the appropriate box.
 - o If more than two official ID's of the same type, enter the additional in one of the Other ID boxes and label accordingly.

Other types of Animal ID

- **Flop Tag/Brands/Tattoos**: Enter ID in the appropriate box, indicating color of the tag if applicable.
- **Brands**: Describe the Brand to the extent possible, and indicate the location of the brand on the animal. (Note: The electronic data entry form will only accept 15 characters. If you need more than 15 characters to describe the Brand, indicate on the electronic data entry form to refer to the paper form for a complete description of the Brand.)
- **Tattoos**: Indicate which ear (R = right, L = left), or other location on the animal, was tattooed and include all alpha/numeric characters.

Note: Color Codes

Please use CAPITAL LETTER for the color of the tag, followed immediately by an underscore (_) and then record whatever is written or printed on the tags.

Y = yellow	R = red
G = green	W = white
B = blue	O = orange
L = purple (lavender)	P = pink
T = tan (brown)	S = silver
K = black	A = gray

Note: For two colored tags, designate the major color in the database but include both colors on the paperwork.

So a yellow plastic bangle tag with the number 49 is "Y_49"

- Enter this information on the electronic version of these forms either on a tablet PC or via the web-based forms unless such electronic entry is impossible.
- Print a copy of the completed BSE Surveillance Submission Form, BSE Surveillance Submission Continuation Form if used, and on each BSE Surveillance Data Collection Form to accompany the samples shipped to the designated laboratory.
- Prepare four (4) copies of these completed forms for further distribution and filing (one for the submitter, one for the collection site, one for the VS Area Office, and one to be maintained with the identification devices).
- Sample collectors will collect all animal identification devices, brands (via digital picture
 or drawing), and tattoos (refrigerate tissue containing tattoo) from each animal sampled.
 Bag these identification items, label them with the sample number and bar code sticker,
 attach a copy of a submission form, and save until the negative results are received for
 the animal sampled.
- The sample submitter will verify, via the overnight contract delivery service tracking system that the submission has been delivered to the designated laboratory. If the sample does not arrive as expected, the submitter should work with delivery service to determine the location and delivery status of the sample. Samples not acceptable for testing will not be counted in the surveillance plan.

Shipping the Sample

Packaging Materials (Supplied from NVSL as BSE Kits)

- Approved shipping box.
- Plastic bag or Zip-loc bag to place sample tubes in.
- USDA BSE Surveillance Submission Form.
- USDA BSE Surveillance Data Collection Form.
- Absorbent material.
- Ice packs.
- (2) bio-hazard bags (to comply with the International Air Transport Association (IATA) shipping regulations)
- Labels for shipping regulations compliance (air eligible, IATA statement, UN 3373, Keep from heat/freezing, Animal Diagnostic Specimen)

Packing and Shipping

- Fill out USDA BSE Surveillance Submission Form (attaching bar code label) and USDA BSE Surveillance Data Collection Form (attaching bar code label) (see Appendix G for guidance on completing forms).
- Place labeled sample tubes into plastic bag with absorbent.
- Place plastic bag into clear bio-hazard bag (STP-741) and seal.
- Place this bag into white bio-hazard bag (STP-740) and seal.
- Place the white bag into your shipping box.
- Place frozen ice packs on top of the bag.
- Place completed USDA BSE Surveillance Submission Form and USDA BSE Surveillance Data Collection Form on top of inner Styrofoam lid.
- Seal box
- Place address shipping label on the box (supplied by local Federal veterinarian); addressed to appropriate laboratory conducting BSE testing for your state.
- Place the other required shipping labels on the box.
- Ship by overnight delivery with the Federal contract service.
- If shipping on a Friday, be sure to mark/label box for Saturday delivery.

Place sample tube on cold packs as soon as possible.

Do NOT freeze!



NVSL supplies a certified shipping box and all supplies need for shipping as BSE kits. To request additional BSE kits, fax a request to number noted below.

If you need further assistance with shipping, you may contact the shipping department at:

National Veterinary Services Laboratories 1800 Dayton Avenue

Ames, IA 50010

Ph: (515) 663-7530 Fax: (515) 663-7378

Designated Laboratories for BSE Sample Submission

NOTE: All highly suspicious cases as defined in VS Memo 580.16 must be sent to NVSL.

State where sample collected	Designated laboratory
All states submitting formalin fixed tissues for	USDA, APHIS, VS, NVSL
IHC testing.	1800 Dayton Ave.
me testing.	Ames, IA 50010
	Ames, 1A 30010
	Steve Growen
	888-273-6875
	bsemailcases@aphis.usda.gov
Texas, Arkansas, Louisiana, New Mexico	Texas A&M University
Texus, Firkunsus, Louisiunu, Ivew Mexico	TVMDL
	Pathology Department
	1 Sippel Road
	College Station, TX 77843
	Conege Station, 171 77013
	Dr. Levle Gayle
	979-845-3414
Washington, Oregon, Idaho, Montana, Hawaii,	Washington State University WADDL
Alaska	Animal Disease Diagnostic Laboratory
	Bustad Hall Room 155-N
	Pullman WA 99164-7034
	Tim Bazzler
	509-335-9696
Georgia, Mississippi, Alabama, Tennessee,	Athens Diagnostic Laboratory
Virginia, North Carolina, South Carolina,	College of Veterinary Medicine
Oklahoma, Florida	University of Georgia
	Athens, GA 30602
	Doris Miller
	706-542-5568
California, Arizona, Nevada	CAHFS-Thurman Bldg
China, Finzona, Frontan	West Health Science Drive
	UC Davis
	Davis, CA 95616
	Dr. Alex Ardans
	530-752-8709
Colorado, Utah, Wyoming, Nebraska, South	Colorado State University
Dakota, North Dakota, Kansas, Missouri,	Veterinary Diagnostic Laboratory
Iowa, Illinois, Indiana, Kentucky, Ohio, West	300 West Drake, Rm. E-100
Virginia, Minnesota, Wisconsin (FSIS only)	Ft. Collins, CO 80526
	Dr. Barbara Powers
	970-297-1281
	710-471-1401

State where sample collected	Designated laboratory
New York, Maine, Maryland, Massachusetts,	Cornell University
New Hampshire, New Jersey, Vermont, Rhode	Animal Health Diagnostic Laboratory
Island, Delaware, Connecticut, Michigan,	College of Veterinary Medicine at Cornell
Pennsylvania	Upper Tower Road
	Ithaca, NY 14853
	Edward J. Dubovi
	607-253-3900
	tselab@cornell.edu
Wisconsin	WVDL – TSE Laboratory
	6101 Mineral Point Rd
	Madison, WI 53705
	Dr. Phil Bochsler
	608-262-5432

Reporting of Laboratory Results

• The designated laboratories will report rapid screening test results back to the sample submitter, the AVIC, and when requested by the AVIC, to the plant management of the facility where the sample was collected. Rapid screening test results will be reported as either: (1) Inconclusive; (2) Not Detected; or (3) No Test. All inconclusive rapid screening test results samples <u>must</u> be immediately forwarded to NVSL for confirmatory testing.

Proper Communication for Submitting Samples

It is essential to have secure and reliable communication among the individuals responsible for sample collection at collection locations, establishments' management, and NVSL or designated laboratories. Sample submitter – designated laboratory communication guidelines are as follows:

• The sample submitter will notify the appropriate laboratory of incoming samples via facsimile, telephone, e-mail, or any other approved electronic method (unless otherwise instructed by that laboratory). This includes when electronic submission of the BSE Surveillance Submission Form is used. The information to be communicated will include the overnight contract delivery service tracking number, the collection site name and address, the unique Referral Number of the submission, and the number of samples. There is currently a dedicated e-mail box for notifying NVSL of incoming samples (bsemailcases@aphis.usda.gov). Sample submitters must accurately record all relevant information on the USDA BSE Surveillance Submission Form, USDA BSE Surveillance Submission Continuation Form if used, and on each of the USDA BSE Surveillance Data

Collection Forms. Enter this information on the electronic version of these forms – either on a tablet PC or via the web-based forms – unless such electronic entry is impossible. Print a copy of the completed BSE Surveillance Submission Form, BSE Surveillance Submission Continuation Form if used, and on each BSE Surveillance Data Collection Form to accompany the samples shipped to the designated laboratory. Prepare four (4) copies of these completed forms for further distribution and filing (one for the submitter, one for the collection site, one for the VS Area Office, and one to be maintained with the identification devices). See Appendix F for instructions on completing the BSE Surveillance Submission Form and BSE Surveillance Data Collection Form. See Appendix G for instructions on using barcodes in shipping the sample.

- The paper version of the BSE Surveillance Submission Form has space to indicate the identification number for 20 animals. If additional animals are sampled, the sample submitter should submit a BSE Surveillance Submission Continuation Form listing the unique identification numbers for each additional animal.
- The sample submitter should verify, via the overnight contract delivery service tracking system that the submission has been delivered to the designated laboratory. If the sample does not arrive as expected, the sample submitter should work with the delivery service to determine the location and delivery status of the sample.
- When FSIS personnel sample antemortem condemned cattle at the official establishment, they will either enter sample data directly into the BSE-SIS system or forward by FAX or e-mail completed BSE-SIS sample collection sheets to the APHIS,VS office with responsibility. APHIS Animal Identification Coordinators (AIC) may assist with sample delivery verification and troubleshooting.

Disposal

- 1. If further processing is intended, carcasses pending test results will be held; then rendered or otherwise processed after negative test results are obtained (could include boning out carcass and holding the meat product for use in pet food or rendering materials and holding finished product). Carcasses pending test results may also be disposed of through burial in a landfill or on-farm, incineration, or alkaline digestion.
 - a. Carcasses and offal from "inconclusive" or positive animals may be disposed of by one of the following:
 - Refrigerate or freeze pending test results then render at dedicated facilities, if available render only for non-animal feed use, such as biofuel or cement.
 - Bury in a landfill or on-the-farm.
 - Use alkaline digestion.
 - Incinerate.

- b. Should a positive animal be found, an indemnity would be supplied for the disposed batches of product.
- c. Hides Hides need not be disposed or held pending test results.
- d. Sample disposal Laboratories will dispose of samples using standard operating procedures.
- 2. All carcasses and offal from sampled animals that are intended for further processing must be held until laboratory test results are received.
 - All agreements with participating facilities require a test and hold arrangement in order to receive payment for any cattle that are sampled.
 - Carcasses or offal transferred after sampling for storage to off-site facilities, etc., must be under documented agreements with USDA APHIS and provide records for traces, as needed to ensure identity.
 - After obtaining negative test results, carcasses and offal may be rendered or otherwise processed (could include boning out carcass and holding the meat product for use in pet food or rendering materials and holding finished product.)
 - Carcasses pending test results may also be disposed of through burial in a landfill or on-farm, incineration, or alkaline digestion.
- 3. The disposal of the carcasses and offal from sampled cattle must be completed in compliance with Federal, State, and local laws.
- 4. Should a positive animal be found, indemnity would be paid for the disposed batches of product.
- 5. If carcass and offal are **not intended for further processing or distribution**, the carcass and offal do not have to be held. Preferable options for the disposal of carcasses and offal from animals that are not intended for further processing or distribution include the following:
 - Render at dedicated facilities for non-animal feed use, such as biofuel or cement.
 - Burial in an approved lined landfill
 - Burial on-the-farm
 - Alkaline digestion
 - Incineration

NOTE:

Previously buried carcass – If a carcass that has been buried is later found to be confirmed positive, coordinate with local and state officials (e.g. Agriculture and Environmental Protection) on whether or not to exhume carcass.

Sample Disposal – Laboratories will dispose of samples using standard operating procedures.

Veterinary Services Memorandum 580.16 serves as the primary guidance for this procedures manual.

Deviations from this SOP must be justified in writing, approved by the Region, and properly documented.

Cost Recovery Fees Guidelines

Cost recovery guidelines are outlined Appendix 3 of VS Memorandum 580.16. The schedule for cost recovery may change periodically. Please refer to that document for the most up to date cost recovery schedule.